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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Legislation and Regulation Committee

From: Staff

Subject: Board Sponsored Legislation

Provided in this packet are copies of bills and analyses of legislation impacting the practice of pharmacy or the board's jurisdiction (**ATTACHMENT B2a**). A brief summary of the measure is included below. Some Items were previously considered by the board and the Board Position noted.

If the committee so chooses, it can reconsider positions previously taken as well as take positions on new legislation to forward to the board for consideration and action at the April 23 & 24 Board Meeting.

1. AB 501 (Swanson and Hancock) Pharmaceutical Devices

Require a pharmaceutical manufacturer whose product is administered for home use through a prefilled syringe, prefilled pen, or other prefilled injection device to provide at no additional charge, a postage prepaid mail-back sharps container for safe disposal of the used device.

Board Position: Support
Status: Senate Health Committee

2. AB 865 (Davis) State Agencies: Live Customer Service Agents

Require all state agencies to answer incoming phone calls within 10 rings by either a live customer service agent or an automated telephone answering equipment which then must include an option to reach a live customer service agent.

Board Position: Neutral
Status: Senate Governmental Organization Committee

3. AB 1394 (Krekorian) Counterfeit: Trademarks

This proposal would strengthen the criminal penalties against counterfeit operations.

Board Position: Support
Status: Senate Judiciary Committee and Public Health Committee

4. AB 1436 (Hernandez) Nurse Practitioners

Revise the educational requirements for qualification or certification as a nurse practitioner and would require a nurse practitioner to be certified by a nationally recognized body approved by the Board of Registered Nursing.

Board Position: None
Status: Senate Business, Professions and Economic Development Committee

5. AB 1587 (De La Torre) Personal Information: Pharmacy

Exclude from the definition of marketing a written communication or written message provided to a pharmacy patient by a pharmacist or pharmacy personnel that meets specified conditions.

Board Position: None
Status: Senate Judiciary Committee

6. AB 1947 (Emmerson) Pharmacy Technicians

Would increase the minimum requirements for licensure as a pharmacy technician to include both certification by the Pharmacy Technician Certification Board as well as either completion of a technician training program or a specified associate's degree. In addition, would require pharmacy technicians to complete 20 hours of continuing education each renewal cycle.

Board Position: None
Status: Hearing Cancelled at the request of the author.

7. AB 2516 (Mendoza) Prescriptions: electronic transmission

Would require a prescriber to ensure that any prescription issued shall be electronically transmitted to the patient's pharmacist of choice, except as specified.

Board Position: None
Status: Assembly Business and Professions Committee

8. AB 2643 (Cook) Drugs and Devices

Would replace references to the United State Pharmacopoeia in relevant sections of the Business and Professions Code, Health and Safety Code, Insurance Code, Penal Code, Public Resources Code and Welfare and Institutions Code.

Board Position: None
Status: Hearing cancelled at the request of the author.

9. AB 2756 (Duvall) Pharmacists: furnishing drugs during an emergency

Makes a nonsubstantive change to Business and Professions Code section 4062.

Board Position: None
Status: Assembly Business and Professions Committee

10. SB 963 (Ridley Thomas) Regulatory Boards: Sunset Review

Delete provisions subjecting boards to review by the Joint Committee on Boards, Commissions, and Consumer Protection and instead make each of those boards subject to review by a

standing policy committee of the Legislature upon request by a Member of the Legislature or the chief of the Office of the Consumer Advocate.

Board Position: None
Status: Assembly Business and Professions Committee

11. SB 1096 (Calderon) Medical Information

Would allow a pharmacy under specified conditions, to mail specified written communications to a patient, without the patient's authorization.

Board Position: Oppose
Status: Senate Health Committee

12. SB 1270 (Cedillo) Pharmacy: dangerous drug and devices pedigree

Would repeal California's serialization and e-pedigree requirements for all prescription drugs and insert an exemption from pedigree requirements for all drugs shipped through the normal distribution channel from any pedigree or serialization requirement.

Board Position: None
Status: Senate Business, Professions and Economic Development Committee

13. AB 1504 (Ridley-Thomas) Antiepileptic drug products: substitution.

Would prohibit a pharmacist from filling a prescription for an antiepileptic drug that is prescribed by its trade, brand or generic name from substituting a drug product without prior notification of the prescriber and a signed consent of the patient or the patient's agent.

Board Position: None
Status: Senate Business, Professions and Economic Development Committee

14. SB 1594 (Steinberg) Bleeding Disorders Clotting Products

Imposes requirements on providers of blood clotting products for home use that are used to treat hemophilia and other bleeding disorders.

Board Position: None
Status: Senate Appropriations Committee

Additional Active Bills

In addition to the above items, below are additional legislative proposals for committee consideration that were inadvertently not included in the agenda for this meeting. Copies of these proposals are included in **ATTACHMENT B2a.** A bill analysis for each of these proposals will be provided at the meeting.

A. AB 2122 (Plescia) Surgical clinics: licensure

Would define the operational, staffing and procedural standards for surgical clinics and would require the board to perform periodic inspections at least once every three years.

Board Position: None
Status: Assembly Appropriations Committee

B. AB 2425 (Coto) State Department of Public Health: water quality: pharmaceuticals

Would require every pharmaceutical manufacturer that does business in California and whose pharmaceutical products have been detected in the drinking water supplies within California to file a report with the State Public Health Officer as specified.

Board Position: None
Status: Assembly Health Committee

Attachment – Agenda Item B2a

Active Bills

- Bill Analysis
- Copy of Language

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 501 **VERSION: As amended March 13, 2008**

AUTHOR: Swanson **SPONSOR: Alameda County Board of Supervisors**

POSITION: Support

SUBJECT: Pharmaceutical devices: hypodermic needle and syringe disposal

EXISTING LAW:

1. Prohibits the disposal of a hypodermic needle or syringe on the grounds of a playground, beach, park, or any public or private elementary school, vocational, junior high or high school.
2. States that a person who knowingly violates this section is guilty of a misdemeanor.
3. Requires that on or after September 1, 2008, no person shall knowingly place home-generated sharps waste in any of the following containers:
   a. Any container used for collection of solid waste or recyclable materials for greenwaste
   b. Any container used for the commercial collection of solid waste or recyclable materials from a business establishment
   c. Any roll-off container used for collectables of solid waste, construction, and demolition debris, greenwaste or other recyclable materials
4. Requires that on or after September 1, 2008, home generated sharps waste shall be transported only in a sharps container, or other container approved by the enforcement agency as managed by one of the following:
   a. A household hazardous waste facility
   b. A "home generated sharps consolidation point"
   c. A medical waste generator's facility
   d. A facility though the use of an approved medical waster mail-back container

THIS BILL WOULD:

1. Make a number of findings and declarations about the medical need and use of prefilled self-injection prescription medications.
2. State that the Legislature has found that sharps mail-back programs approved by the U.S. Postal Service offer one of the most convenient means for collecting and destroying home-generated sharps and that cooperative efforts of the pharmaceutical industry is necessary to develop a safe needle disposal system.
3. Require a pharmaceutical manufacturer to arrange to provide a postage prepaid, mail-back sharps container that has been approved by the U.S. Postal Service and the Department of Public Health as requested by a consumer of a prefilled syringe, prefilled pen, or other prefilled injection device administered at home.
4. ***As amended 3/13/2008.*** Allow a pharmaceutical manufacturer to provide its consumers concise information on ~~convenient locally available safe needle disposal options.~~ safe disposal alternatives and options for sharps.
5. Defines "sharps container" consistent with the definition in Health and Safety Code Section 117750.

AUTHOR'S INTENT

This bill is intended as a continuation of the legislation regarding the safe needle program - - and to further that purpose. Consumers currently do not have a safe way to dispose of used needles and syringes.

PRIOR HISTORY/RELATED BILLS

SB 1305 (Figueroa) Chapter 64, Statutes of 2006 – Prohibits, as of January 1, 2008, a person from placing home-generated sharps waste in specified commercial and residential solid waste collection containers, including containers used for recyclable materials or greenwaste as well as roll-off containers used for construction and demolition debris. It also requires that home generated-sharps waste be transported in an approved sharps container with an approved facility approved by the Department of Toxics and removes home generated sharps waste as among those items subject to the state's medical waste control laws. The board had no position on this legislation.

FISCAL IMPACT

The board does not anticipate any substantial fiscal impact on its operations. Any minor impact could be absorbed within existing resources.

HISTORY:

Dates	Actions
03/13/08	Mar. 13 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
02/07/08	Feb. 7 Referred to Com. on HEALTH.
01/30/08	Jan. 30 In Senate. Read first time. To Com. on RLS. for assignment.
01/29/08	Jan. 29 Read third time, amended, and returned to third reading. (Page 3855.). Assembly Rule 69(d) suspended. Read third time, passed, and to Senate. (Ayes 45. Noes 27. Page 3871.)
01/17/08	Jan. 17 Read second time. To third reading.
01/16/08	Jan. 16 From committee: Do pass. (Ayes 9. Noes 6.) (January 15).
01/10/08	Jan. 10 Re-referred to Com. on HEALTH.
01/09/08	Jan. 9 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
01/08/08	Jan. 8 Re-referred to Com. on HEALTH.
01/07/08	Jan. 7 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
06/25/07	June 25 Re-referred to Com. on HEALTH.
06/21/07	June 21 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
05/08/07	May 8 In committee: Set, second hearing. Hearing canceled at the request of author.
05/01/07	May 1 In committee: Set, first hearing. Hearing canceled at the request of author.
05/01/07	May 1 Re-referred to Com. on HEALTH.
04/30/07	Apr. 30 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
03/22/07	Mar. 22 Referred to Com. on HEALTH.
02/21/07	Feb. 21 From printer. May be heard in committee March 23.
02/20/07	Feb. 20 Read first time. To print.

Revised March 31, 2008

AMENDED IN SENATE MARCH 13, 2008

AMENDED IN ASSEMBLY JANUARY 29, 2008

AMENDED IN ASSEMBLY JANUARY 9, 2008

AMENDED IN ASSEMBLY JANUARY 7, 2008

AMENDED IN ASSEMBLY JUNE 21, 2007

AMENDED IN ASSEMBLY APRIL 30, 2007

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 501

Introduced by Assembly Members Swanson and Hancock (Coauthor: Assembly Member Dymally)

February 20, 2007

An act to add Section 118288 to the Health and Safety Code, relating to pharmaceutical devices.

LEGISLATIVE COUNSEL'S DIGEST

AB 501, as amended, Swanson. Pharmaceutical devices.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Under existing law, certain items, such as home-generated sharps waste, as defined, are specifically excluded from the definition of medical waste. The act prohibits, on or after September 1, 2008, a person from knowingly placing home-generated sharps waste in certain types of containers, provides that home-generated sharps waste is to be transported only in a sharps container, as defined, or other container approved by the department

or local enforcement agency, and requires this waste to only be managed at specified locations consistent with existing law.

This bill would require a pharmaceutical manufacturer whose product is administered for home use through a prefilled syringe, prefilled pen, or other prefilled injection device to arrange to provide, upon request from a consumer, a postage prepaid, mail-back sharps container that has been approved by the United States Postal Service and the department or a sharps container for the safe storage and transport of sharps to a sharps consolidation location approved by the department or a clinic, physician, or pharmacy that accepts home-generated sharps waste, along with concise information on ~~specified disposal~~ *safe disposal alternatives and* options *for sharps*.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) An estimated 1 million Californians must self-inject prescription medications annually to treat a broad range of serious health problems.

(b) The use of prefilled syringes, prefilled pens, and other prefilled devices with needles is an effective method of prescription drug delivery and is expected to increase significantly in the future. Prefilled syringes, prefilled pens, and other prefilled devices with needles are clearly identified and linked to specific pharmaceutical manufacturers for the provision of their product to California residents.

(c) The increased use of prefilled syringes, prefilled pens, and other prefilled devices with needles will generate millions of home-generated sharps each year. Prefilled pen devices are being used for the treatment of some of the most serious health conditions such as HIV/AIDS, hepatitis C, and many other diseases. If improperly disposed in solid waste and recycling containers these needles will result in significant public health risks.

(d) The Legislature has found that sharps mail-back programs utilizing containers and packaging approved by the United States Postal Service offer one of the most convenient means for collecting and destroying home-generated sharps and that the

cooperative efforts of the pharmaceutical industry are needed to develop a safe needle disposal system for California.

SEC. 2. Section 118288 is added to the Health and Safety Code, to read:

118288. (a) Upon request of a consumer of a prefilled syringe, prefilled pen, or other prefilled injection device administered at home, a pharmaceutical manufacturer shall arrange to provide the consumer with either of the following:

(1) A postage prepaid, mail-back sharps container that has been approved by the United States Postal Service and the State Department of Public Health.

(2) A sharps container for the safe storage of, and transport to, a sharps consolidation location that is approved by the State Department of Public Health or to a clinic, physician, or pharmacy that accepts home-generated sharps waste. This sharps container shall be provided with concise information on ~~the closest available safe sharps disposal sites~~ *safe disposal alternatives and options for sharps*.

(b) For purposes of this section, "sharps container" has the same meaning as in Section 117750.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 865 **VERSION: As amended January 22, 2008**

AUTHOR: Davis **SPONSOR: Author**

BOARD POSITION: Neutral

SUBJECT: State agencies, live customer service agents

EXISTING LAW:

1. Requires each state agency to establish a procedure to ensure that incoming calls on any public line will be answered within 10 rings during regular business hours.

THIS BILL WOULD:

1. **As amended 1/22/08.** Require the headquarter for each state agency to answer telephone calls on ~~any~~ its main public line by a live customer service agent within 10 rings during regular business hours or an automated answering service. If an automated answering service is used, an option must be available to the caller to speak with a life customer service agent.
2. Provide exemptions to ~~field offices and~~ telephone lines dedicated as hotlines for emergency services or others as specified.
3. Define headquarters as the office or agency located in Sacramento, or where the director or head of the agency is located.
4. Defines "main public line" means the line designated by the director or head of the agency as its main public line.

AUTHOR'S INTENT

This legislation is to address the general frustration some constituents experience trying to access a live agent to speak with. Illinois enacted a similar requirement in 2005.

FISCAL IMPACT

Should this bill be enacted, the board will need to pursue a part-time office assistant to help assist board receptionists during peak calling times, (e.g., Mondays, during renewal cycles etc.).

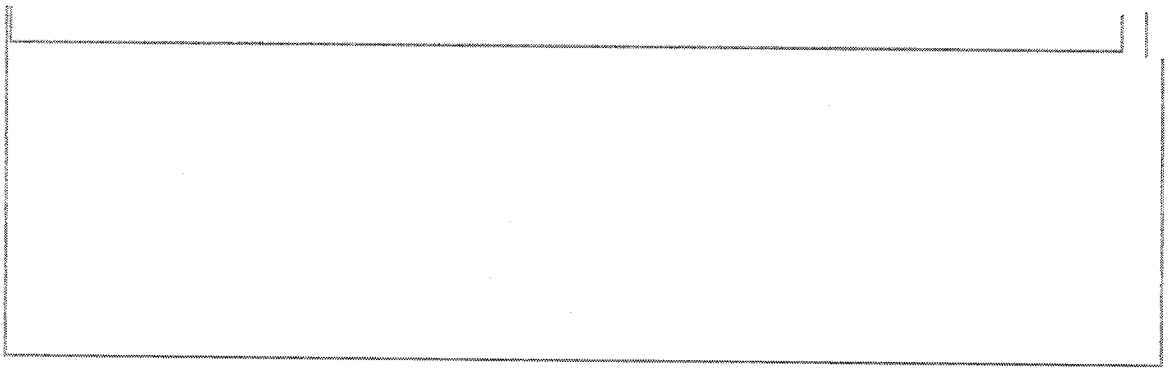
COMMENTS

The board's main public number is currently automated with the use of a phone tree. Callers are advised at the beginning of the recorded message of the option to zero-out to speak with a board receptionist. This proposal would require the board to eliminate the use of the phone tree resulting in additional staff resources to respond to incoming calls. Because of limitations with the current phone system, staff is not aware of a new incoming call when the line is already in use.

The author's office indicates that there may be room to negotiate a requirement similar to the Illinois legislation.

HISTORY:

02/07/08	Feb. 7 Referred to Com. on G.O.
01/28/08	Jan. 28 In Senate. Read first time. To Com. on RLS. for assignment.
01/28/08	Jan. 28 Read third time, passed, and to Senate. (Ayes 76. Noes 0. Page 3835.)
01/24/08	Jan. 24 From committee: Do pass. (Ayes 16. Noes 0. Page 3814.) (January 24). Read second time. To third reading.
01/23/08	Jan. 23 Re-referred to Com. on APPR.
01/22/08	Jan. 22 From committee chair, with author's amendments: Amend, and re-refer to Com. on APPR. Read second time and amended.
01/18/08	Jan. 18 Re-referred to Com. on APPR.
01/17/08	Jan. 17 Read second time and amended.
01/16/08	Jan. 16 From committee: Amend, do pass as amended, and re-refer to Com. on APPR. (Ayes 10. Noes 0.) (January 15).
04/24/07	Apr. 24 Re-referred to Com. on B. & P.
04/23/07	Apr. 23 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
04/17/07	Apr. 17 In committee: Set, second hearing. Hearing canceled at the request of author.
04/10/07	Apr. 10 In committee: Set, first hearing. Hearing canceled at the request of author.
03/12/07	Mar. 12 Referred to Com. on B. & P.
02/23/07	Feb. 23 From printer. May be heard in committee March 25.
02/22/07	Feb. 22 Read first time. To print.



AMENDED IN ASSEMBLY JANUARY 22, 2008

AMENDED IN ASSEMBLY JANUARY 17, 2008

AMENDED IN ASSEMBLY APRIL 23, 2007

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 865

Introduced by Assembly Member Davis

February 22, 2007

An act to amend Section 11022 of the Government Code, relating to state agencies.

LEGISLATIVE COUNSEL'S DIGEST

AB 865, as amended, Davis. State agencies: live customer service agents.

Existing law requires each state agency to establish a procedure whereby incoming telephone calls on any public line shall be answered within 10 rings during regular business hours, subject to certain exceptions.

This bill would name these provisions the State Agency Live Customer Service Act. It would require each state agency to answer an incoming call on ~~any~~ *its* main public line with a live customer service agent or automated telephone answering equipment with an automated prompt that allows a caller to select the option to speak with a live customer service agent, subject to certain exceptions.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 11022 of the Government Code is amended to read:

11022. (a) This section shall be known and may be cited as the State Agency Live Customer Service Act.

(b) Each state agency shall establish a procedure pursuant to which incoming telephone calls on ~~any~~ *the* main public line shall be answered by a live customer service agent, or automated telephone answering equipment in accordance with subdivision (c), within 10 rings during regular business hours as set forth in Section 11020, except when emergency or illness requires adjustments to normal staffing levels.

(c) During regular business hours, as set forth in Section 11020, the headquarters of every state agency that uses automated telephone answering equipment shall have for all incoming telephone calls on ~~a~~ *the* main public line, an automated prompt that allows a caller to select the option to speak with a live customer service agent and shall have a live customer service agent available for this purpose.

(d) Subdivision (c) does not apply to ~~the following:~~

~~(1) Field offices.~~

~~(2) Telephone~~ *telephone* lines dedicated as hotlines for emergency services, telephone lines dedicated exclusively to providing general information, and any system that is designed to permit an individual to conduct a complete transaction with a state agency over the telephone solely by pressing one or more touch-tone telephone keys in response to automated prompts.

(e) For the purposes of this section, the following definitions shall apply:

(1) "Headquarters" means the chief executive office of the agency designated by the director or head of the agency as its main office.

(2) "Main public line" means ~~——~~ *the line designated by the director or head of the agency as its main public line.*

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1394 VERSION: As amended January 9, 2008

AUTHOR: Krekorian SPONSOR: California Chamber of Commerce

BOARD POSITION: Support

SUBJECT: Counterfeit Trademarks

EXISTING LAW:

1. Prohibits the manufacture, sale and possession for sale of counterfeit products as specified in Penal Code §350.
2. Establishes the penalties for an offense and sets fine amounts of $250,000 for individuals and $500,000 for corporations for an offense that involves 1,000 or articles.
3. Requires as part of a conviction or a plea of nolo contendere, the forfeiture and destruction of all of those marks and of all goods, articles and other matter being marks used in connection with, or were part of any violation.
4. Defines counterfeit mark.

THIS BILL WOULD:

1. Also prohibit transport, offers for sale, distribution of counterfeit products. Make it a misdemeanor or a felony for a person to intentionally transport, offer for sale, or distribute any counterfeit registered trademark, as specified.
2. Will enhance the penalties for violation by a person to include a fine note to exceed $250,000 or three times the total retail or fair market value of the articles described and will enhance the penalties for violation by a corporation to include a fine not to exceed $500,000 or three times the total retail or fair Market value of the articles described in this subdivision.
3. Require as part of a conviction or a plea of nolo contendere, the forfeiture of all proceeds of the crime.
4. Expand the definition of a counterfeit mark to also include not only those marks used, but also those intended to be used. Clarify that

when counterfeited but unassembled components of any articles are recovered, the number of articles shall be equivalent to the number of completed articles that could have been made from those components.

5. Expand the unassembled components of articles to be included then determining the value that could have been made from the components.
6. Require the court to order a convicted person of an offense to pay restitution to the trademark owner or other victim of the offense including restitution for any economic loss as well as expenses incurred by the owner in the investigation and prosecution of the offense.
7. Shall not be enforced against any party who engages in fair uses of a mark, as specified in Section 14247 of the Business and Professions Code.

AUTHOR'S INTENT

According to the Sponsor, current law is unclear and lacks consistency with federal law. Several unclear provisions create loopholes that undermine enforcement efforts. In addition, current state law caps the monetary penalties. This proposal will require consideration of the potential profits of the counterfeit operation.

COMMENT

This proposal would strengthen the criminal penalties against counterfeit operations and meshes with our public protection mandate and e-pedigree requirements.

FISCAL IMPACT

The board does not anticipate any substantial fiscal impact on its operations. Any minor impact could be absorbed within existing resources.

HISTORY:

02/07/08 Feb. 7 Referred to Coms. on JUD. and PUB. S.

01/28/08 Jan. 28 In Senate. Read first time. To Com. on RLS. for assignment.

01/28/08 Jan. 28 Read third time, passed, and to Senate. (Ayes 75. Noes 0. Page 3840.)

01/24/08 Jan. 24 In committee: Set, first hearing. Referred to APPR. suspense file. From committee: Do pass. (Ayes 16. Noes 0. Page 3814.) (January 24). Read second time. To third reading.

01/16/08 Jan. 16 From committee: Do pass, and re-refer to Com. on APPR. with

recommendation: To Consent Calendar. Re-referred. (Ayes 7. Noes 0.) (January 15).

01/10/08 Jan. 10 Re-referred to Com. on PUB. S.

01/09/08 Jan. 9 From committee chair, with author's amendments: Amend, and re-refer to Com. on PUB. S. Read second time and amended.

01/08/08 Jan. 8 Re-referred to Com. on PUB. S.

01/07/08 Jan. 7 From committee chair, with author's amendments: Amend, and re-refer to Com. on PUB. S. Read second time and amended.

03/22/07 Mar. 22 Referred to Com. on PUB. S.

02/26/07 Feb. 26 Read first time.

02/25/07 Feb. 25 From printer. May be

02/26/07 Feb. 26 Read first time.

02/25/07 Feb. 25 From printer. May be heard in committee March 27.

02/23/07 Feb. 23 Introduced. To

AMENDED IN ASSEMBLY JANUARY 9, 2008

AMENDED IN ASSEMBLY JANUARY 7, 2008

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 1394

Introduced by Assembly Member Krekorian

February 23, 2007

An act to amend Section 350 of the Penal Code, relating to counterfeiting.

LEGISLATIVE COUNSEL'S DIGEST

AB 1394, as amended, Krekorian. Counterfeit: trademarks.

Existing law makes it a misdemeanor or a felony for a person to willfully manufacture, intentionally sell, or knowingly possess for sale any counterfeit registered trademark, as specified. Existing law also provides, upon conviction, for the forfeiture and destruction of all the counterfeit trademarks and related articles, as specified. Existing law regarding counterfeited trademarks also applies to unassembled components of computer software packages. Under existing law, a court is required to order restitution, as specified, to a victim of a crime.

This bill would, in addition, make it a misdemeanor or a felony for a person to *intentionally* transport, offer for sale, or distribute any counterfeit registered trademark, as specified. This bill would also increase the maximum fine allowed to be imposed upon conviction. This bill would require the forfeiture of all proceeds from the willful manufacture, *intentional* transport, ~~intentional~~ sale, offering for sale, distribution, or knowing possession for sale of any counterfeit registered trademark. This bill would also apply provisions related to counterfeited

trademarks to unassembled components, as specified, *and would require restitution to be paid to the victim of a trademark offense.*

Because this bill would expand the definition of an existing crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 350 of the Penal Code is amended to read:

350. (a) Any person who willfully manufactures, *intentionally* transports, ~~intentionally~~ sells, offers for sale, *or* distributes, or knowingly possesses for sale any counterfeit of a mark registered with the Secretary of State or registered on the Principal Register of the United States Patent and Trademark Office, shall, upon conviction, be punishable as follows:

(1) When the offense involves less than 1,000 of the articles described in this subdivision, with a total retail or fair market value less than that required for grand theft as defined in Section 487, and if the person is an individual, he or she shall be punished by a fine of not more than five thousand dollars ($5,000), or by imprisonment in a county jail for not more than one year, or by both that fine and imprisonment; or, if the person is a corporation, by a fine of not more than one hundred thousand dollars ($100,000).

(2) When the offense involves 1,000 or more of the articles described in this subdivision, or has a total retail or fair market value equal to or greater than that required for grand theft as defined in Section 487, and if the person is an individual, he or she shall be punished by imprisonment in a county jail not to exceed one year, or in the state prison for 16 months, or two or three years, or by a fine not to exceed the greater of two hundred fifty thousand dollars ($250,000), or three times the total retail or fair market value of the articles described in this subdivision, or

by both that imprisonment and fine; or, if the person is a corporation, by a fine not to exceed the greater of five hundred thousand dollars ($500,000) or three times the total retail or fair market value of the articles described in this subdivision.

(b) Any person who has been convicted of a violation of either paragraph (1) or (2) of subdivision (a) shall, upon a subsequent conviction of paragraph (1) of subdivision (a), if the person is an individual, be punished by a fine of not more than fifty thousand dollars ($50,000), or by imprisonment in a county jail for not more than one year, or in the state prison for 16 months, or two or three years, or by both that fine and imprisonment; or, if the person is a corporation, by a fine of not more than two hundred thousand dollars ($200,000).

(c) Any person who has been convicted of a violation of subdivision (a) and who, by virtue of the conduct that was the basis of the conviction, has directly and foreseeably caused death or great bodily injury to another through reliance on the counterfeited item for its intended purpose shall, if the person is an individual, be punished by a fine of not more than fifty thousand dollars ($50,000), or by imprisonment in the state prison for two, three, or four years, or by both that fine and imprisonment; or, if the person is a corporation, by a fine of not more than two hundred thousand dollars ($200,000).

(d) In any action brought under this section resulting in a conviction or a plea of nolo contendere, the court shall order the forfeiture and destruction of all of those marks and of all goods, articles, or other matter bearing the marks, and the forfeiture and destruction or other disposition of all means of making the marks, and any and all electrical, mechanical, or other devices for manufacturing, reproducing, transporting, or assembling these marks, that were used in connection with, or were part of, any violation of this section, and the forfeiture of all proceeds of the crime. However, no vehicle shall be forfeited under this section that may be lawfully driven on the highway with a class 3 or 4 license, as prescribed in Section 12804 of the Vehicle Code, and that is any of the following:

(1) A community property asset of a person other than the defendant.

(2) The sole class 3 or 4 vehicle available to the immediate family of that person or of the defendant.

(3) Reasonably necessary to be retained by the defendant for the purpose of lawfully earning a living, or for any other reasonable and lawful purpose.

(e) For the purposes of this section, the following definitions shall apply:

(1) When counterfeited but unassembled components of computer software packages are recovered, including, but not limited to, counterfeited computer diskettes, instruction manuals, or licensing envelopes, the number of "articles" shall be equivalent to the number of completed computer software packages that could have been made from those components.

(2) "Counterfeit mark" means a spurious mark that is identical with, or confusingly similar to, a registered mark and is used, or intended to be used, on or in connection with the same type of goods or services for which the genuine mark is registered. It is not necessary for the mark to be displayed on the outside of an article for there to be a violation. For articles containing digitally stored information, it shall be sufficient to constitute a violation if the counterfeit mark appears on a video display when the information is retrieved from the article. The term "spurious mark" includes genuine marks used on or in connection with spurious articles and includes identical articles containing identical marks, where the goods or marks were reproduced without authorization of, or in excess of any authorization granted by, the registrant. When counterfeited but unassembled components of any articles described under subdivision (a) are recovered, including, but not limited to, labels, patches, fabric, stickers, wrappers, badges, emblems, medallions, charms, boxes, containers, cans, cases, hangtags, documentation, or packaging, or any other components of any type or nature that are designed, marketed, or otherwise intended to be used on or in connection with any articles described under subdivision (a), the number of "articles" shall be equivalent to the number of completed articles that could have been made from those components.

(3) "Knowingly possess" means that the person possessing an article knew or had reason to believe that it was spurious, or that it was used on or in connection with spurious articles, or that it was reproduced without authorization of, or in excess of any authorization granted by, the registrant.

(4) "Registrant" means any person to whom the registration of a mark is issued and that person's legal representatives, successors, or assigns.

(5) "Sale" includes resale.

(6) "Value" has the following meanings:

(A) When counterfeit items of computer software are manufactured or possessed for sale, the "value" of those items shall be equivalent to the retail price or fair market price of the true items that are counterfeited.

(B) When counterfeited but unassembled components of computer software packages or any other articles described under subdivision (a) are recovered, including, but not limited to, counterfeited digital disks, instruction manuals, licensing envelopes, labels, patches, fabric, stickers, wrappers, badges, emblems, medallions, charms, boxes, containers, cans, cases, hangtags, documentation, or packaging, or any other components of any type or nature that are designed, marketed, or otherwise intended to be used on or in connection with any articles described under subdivision (a), the "value" of those components shall be equivalent to the retail price or fair market value of the number of completed computer software packages or other completed articles described under subdivision (a) that could have been made from those components.

(C) "Retail or fair market value" of a counterfeit article means a value equivalent to the retail price or fair market value, as of the last day of the charged crime, of a completed similar genuine article containing a genuine mark.

(f) This section shall not be enforced against any party who has adopted and lawfully used the same or confusingly similar mark in the rendition of like services or the manufacture or sale of like goods in this state from a date prior to the earliest effective date of registration of the service mark or trademark either with the Secretary of State or on the Principle Register of the United States Patent and Trademark Office.

(g) An owner, officer, employee, or agent who provides, rents, leases, licenses, or sells real property upon which a violation of subdivision (a) occurs shall not be subject to a criminal penalty pursuant to this section, unless he or she sells, or possesses for sale, articles bearing a counterfeit mark in violation of this section.

This subdivision shall not be construed to abrogate or limit any civil rights or remedies for a trademark violation.

(h) This section shall not be enforced against any party who engages in fair uses of a mark, as specified in Section 14247 of the Business and Professions Code.

~~(h)~~

(i) When a person is convicted of an offense under this section, the court shall order the person to pay restitution to the trademark owner and any other victim of the offense pursuant to Section 1202.4. In determining the value of the economic loss in a case involving an offense against the trademark owner, a court shall grant restitution for any and all economic loss, including, but not limited to, expenses incurred by the trademark owner in the investigation ~~and prosecution~~ of the offense.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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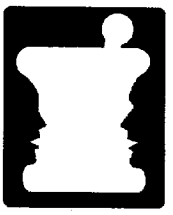
CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 1436 **VERSION: As amended January 7, 2008**

AUTHOR: Hernandez **SPONSOR: CA Association for Nurse Practitioners**

BOARD POSITION: None

SUBJECT: Nurse practitioners: scope of practice.

EXISTING LAW:

1. Defines the scope of practice for nurse practitioners.
2. Allows a nurse practitioner to dispense drugs pursuant to a protocol and specifies the conditions under which this can be done.
3. Details the requirements for a certificate evidencing that a person is qualified as a nurse practitioner.
4. Specifies the information required on a written order for a prescriber.

THIS BILL WOULD:

1. Revise the education requirement for an initial qualification or certification as a nurse practitioner to include either a master's degree or a doctoral degree in nursing.
2. Require satisfactory completion of a nurse practitioner program approved by the board.
3. Require that the nurse practitioner be certified by a nationally recognized certifying body approved by the board.

AUTHOR'S INTENT:

The board is awaiting a response from the author's office.

PRIOR HISTORY/RELATED BILLS:

Prior to amendment, this bill contained several of the provisions found in SB 809. This bill was amended and is requiring annual certification as a nurse practitioner as well as allowing a nurse practitioner to use a doctoral degree in nursing as a qualification method.

FISCAL IMPACT:

The board does not anticipate any fiscal impact.

COMMENTS:

The board did not take a position on this legislation previously; however, earlier discussions by the board about this legislation included concern about the potential increase in prescription errors by nurse practitioners. As amended, the scope of practice issues has been removed.

HISTORY:

Dates	Actions
02/07/08	Feb. 7 Referred to Com. on B., P. & E.D.
01/30/08	Jan. 30 In Senate. Read first time. To Com. on RLS. for assignment.
01/29/08	Jan. 29 Read third time, passed, and to Senate. (Ayes 76. Noes 0. Page 3883.)
01/24/08	Jan. 24 From committee: Do pass. To Consent Calendar. (January 24). Read second time. To Consent Calendar.
01/15/08	Jan. 15 From committee: Do pass, and re-refer to Com. on APPR. with recommendation: To Consent Calendar. Re-referred. (Ayes 10. Noes 0.) (January 15).
01/08/08	Jan. 8 Re-referred to Com. on B. & P.
01/07/08	Jan. 7 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
05/31/07	May 31 Re-referred to Com. on B. & P.
05/30/07	May 30 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
04/24/07	Apr. 24 In committee: Set, first hearing. Hearing canceled at the request of author.
04/23/07	Apr. 23 Joint Rule 62(a), file notice waived. (Page 1106.)
04/18/07	Apr. 18 Re-referred to Com. on B. & P.
04/17/07	Apr. 17 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
04/10/07	Apr. 10 Re-referred to Com. on B. & P.
04/09/07	Apr. 9 Referred to Coms. on B. & P. and HEALTH. From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
02/26/07	Feb. 26 Read first time.
02/25/07	Feb. 25 From printer. May be heard in committee March 27.
02/23/07	Feb. 23 Introduced. To print.

AMENDED IN ASSEMBLY JANUARY 7, 2008

AMENDED IN ASSEMBLY MAY 30, 2007

AMENDED IN ASSEMBLY APRIL 17, 2007

AMENDED IN ASSEMBLY APRIL 9, 2007

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 1436

Introduced by Assembly Member Hernandez
(Coauthor: Assembly Member Niello)

February 23, 2007

An act to amend ~~Sections 2725, 2725.1,~~ *Section* 2835.5~~, and 2836.1 of, and to add Section 2835.7 to,~~ *of* the Business and Professions Code, relating to the nursing.

LEGISLATIVE COUNSEL'S DIGEST

AB 1436, as amended, Hernandez. Nurse practitioners~~: scope of practice~~.

Existing law, the Nursing Practice Act, provides for the certification and regulation of nurse practitioners and nurse-midwives by the Board of Registered Nursing and specifies requirements for *qualification or* certification as a nurse practitioner. ~~Under the act, the practice of nursing is defined, in part, as providing direct and indirect patient care service ordered by specified healing arts practitioners, including dispensing of drugs or devices upon their order in a clinic setting, as defined.~~

~~This bill would specify that the practice of nursing includes those actions taken pursuant to an order by a nurse practitioner or a nurse-midwife. The bill would provide that a nurse practitioner is authorized to perform comprehensive health care services for which he~~

~~or she is educationally prepared and competent to perform and to admit and discharge patients from health facilities in collaboration, as defined, with specified healing arts practitioners. The bill would deem specified authorizations by a physician and surgeon to include authorizations provided by a certified nurse practitioner. The bill would require a certified nurse practitioner to consult or refer a patient to another health care provider if a situation or condition occurs beyond the nurse practitioner's knowledge and experience. The~~

This bill would revise the educational requirements for *qualification or* certification as a nurse practitioner and would require a nurse practitioner to be certified by a nationally recognized certifying body approved by the board.

~~Because this bill would impose additional requirements under the Nursing Practice Act, the violation of which would be a crime, it would impose a state-mandated local program.~~

~~The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.~~

~~This bill would provide that no reimbursement is required by this act for a specified reason.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: ~~yes~~ *no*.

The people of the State of California do enact as follows:

SECTION 1. Section 2835.5 of the Business and Professions Code is amended to read:

2835.5. (a) A registered nurse who is holding himself or herself out as a nurse practitioner or who desires to hold himself or herself out as a nurse practitioner shall, within the time prescribed by the board and prior to his or her next license renewal or the issuance of an initial license, submit educational, experience, and other credentials and information as the board may require for it to determine that the person qualifies to use the title "nurse practitioner," pursuant to the standards and qualifications established by the board.

(b) Upon finding that a person is qualified to hold himself or herself out as a nurse practitioner, the board shall appropriately indicate on the license issued or renewed, that the person is qualified to use the title "nurse practitioner." The board shall also

issue to each qualified person a certificate evidencing that the person is qualified to use the title "nurse practitioner."

(c) A person who has been found to be qualified by the board to use the title "nurse practitioner" prior to the effective date of this section, shall not be required to submit any further qualifications or information to the board and shall be deemed to have met the requirements of this section.

(d) ~~On and after January 1, 2008, an~~ *An* applicant for initial qualification or certification as a nurse practitioner under this article who has not been qualified or certified as a nurse practitioner in California or any other state shall meet the following requirements:

(1) Hold a valid and active registered nursing license issued under this chapter.

(2) Possess a master's degree ~~in nursing, a master's degree in a clinical field related to nursing, or a graduate~~ *or doctoral* degree in nursing.

(3) Satisfactorily complete a nurse practitioner program approved by the board.

(4) Be certified as a nurse practitioner by a nationally recognized certifying body approved by the board.

~~SECTION 1. Section 2725 of the Business and Professions Code is amended to read:~~

All matter omitted in this version of the bill appears in the bill as amended in the Assembly 05/30/07. (JR11)

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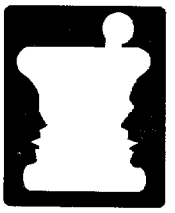
CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 1587 **VERSION: As Amended August 20, 2007**

AUTHOR: De La Torre **SPONSOR: Congress of California Seniors**

BOARD POSITION: None

SUBJECT: Personal information: pharmacy.

EXISTING LAW:

1. Defines "marketing" as a communication about a product or service that encourages recipients of the communication to purchase or use the product of service.
2. Details exemptions to the definition to include:
   - Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration
   - Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network.
   - Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about, among other things, treatment options. Such communications may result in direct or indirect remuneration if the individual receiving the communication is notified of such, in a typeface no smaller that 14-point font.

THIS BILL WOULD:

1. Also exempt a written communication or message provided to a pharmacy patient during a face-to-face interaction with a pharmacist or pharmacy personnel, if all of the following apply:
   - The communication does not involve the sale or transfer of individually identifiable patient information
   - The communication assists the pharmacist or pharmacy personnel in the transmittal of use information regarding a prescription drug dispensed to the patient
   - The content of the communication provides information about the dispensed drug, another treatment or therapy for a disease or health condition for which the drug is dispensed or a drug dispensed within the last three years, general information about a health condition for which the patient's disease may put the patient at risk, or general information about a health condition for which the patient may be at risk given the age or gender of the patient.

- The pharmacist is available upon request of the patient to answer questions regarding the communication
- If the communication is paid for, the communication must also include, among other things, the source of the sponsorship in typeface no smaller than 14-point type.
- The communication contains instruction in typeface no smaller than 14-point font, describing how the patient can opt out of the portion of the communication that is an advertisement paid for.
- The communication does not involve the sale or transfer to medical information by or to the pharmacy by another entity and the communication is based only on medical information that has already been provided to and maintained by the pharmacist.

AUTHOR'S INTENT

This bill is intended to clarify the existing statute and would exempt drug information from the definition of "marketing communications."

FISCAL IMPACT:

The board does not anticipate any major fiscal impact to the board. Any minor impact could most likely be absorbed with existing resources.

SUPPORT and OPPOSITION:

Support

National Association of Chain Drug Stores
National Council on Patient Information and Education
National Consumers League
CA Retailers Association
Coalition for Healthcare Communication
Embracing Wellness
AIDS Legal Referral Panel
STOP AIDS Project
Marin AIDS Project
Pacific Center for Human Growth
Greenlining Institute
AIDS Emergency Fund & Breast Cancer Emergency Fund
Mission Neighborhood Health Center

Opposition
Consumers Union
Southern CA HIV Advocacy Coalition
Pfizer, Inc.
World Privacy Forum

COMMENTS:

The intent of this legislation is to provide additional information to consumers. However the board may want to consider if is appropriate for a pharmacist to provide a patient with drug information on a medication that is not being dispensed by the pharmacist and if this undermines the value of patient consultation. Also, it is unclear who is responsible for the enforcement of these provisions.

This bill is inactive.

HISTORY:

Dates	Actios
01/31/08 Jan. 31 Re-referred to Com. on JUD.	
11/28/07 Nov. 28 Withdrawn from committee. Re-referred to Com. on RLS.	
08/20/07 Aug. 20 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on E., R. & C.A.	
07/20/07 July 20 In committee: Hearing postponed by committee. Joint Rule 62(a), file notice waived. (Page 1917.)	
07/19/07 July 19 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on E., R. & C.A. In committee: Hearing postponed by committee.	
07/17/07 July 17 Withdrawn from committee. Re-referred to Com. on RLS. Re-referred to Com. on E., R. & C.A.	
07/16/07 July 16 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on JUD.	
07/10/07 July 10 In committee: Set first hearing. Failed passage. Reconsideration granted.	
06/27/07 June 27 Read second time, amended, and re-referred to Com. on JUD.	

06/26/07	June 26 From committee: Amend, do pass as amended, and re-refer to Com. on JUD. (Ayes 6. Noes 2.) .
06/07/07	June 7 Referred to Coms. on HEALTH and JUD.
05/24/07	May 24 In Senate. Read first time. To Com. on RLS. for assignment.
05/24/07	May 24 Read third time, passed, and to Senate. (Ayes 70. Noes 6. Page 1615.)
05/21/07	May 21 Read third time, amended, and returned to third reading. (Page 1565.).
05/09/07	May 9 Read second time. To third reading.
05/08/07	May 8 Read second time and amended. Ordered returned to second reading.
05/07/07	May 7 From committee: Amend, and do pass as amended. (Ayes 15. Noes 0.) (May 1).
03/29/07	Mar. 29 Referred to Com. on HEALTH.
02/26/07	Feb. 26 Read first time.
02/25/07	Feb. 25 From printer. May be heard in committee March 27.
02/23/07	Feb. 23 Introduced. To print.

CapitolTrack

BACK

AB 1587 De La Torre Personal information: pharmacy.

Status: 1/31/2008 Re-referred to Com. on JUD.

Current Location: 1/31/2008 S-JUD.

Dead/2YR | 1st Desk | 1st Policy | 1st Fiscal | 1st Floor | 2nd Desk | 2nd Policy | 2nd Fiscal | 2nd Floor | Conf./Conc. | Enrolled | Vetoed | Chaptered

Status History Short Summary Long Summary User Summary Digest

Calendar

Manage Bills add notification
edit /// archive

Bill Text

Amended - 8/20/2007	html pdf word
Amended - 7/19/2007	html pdf word
Amended - 7/16/2007	html pdf word
Amended - 6/27/2007	html pdf word
Amended - 5/21/2007	html pdf word
Amended - 5/8/2007	html pdf word
Introduced - 2/23/2007	html pdf word

Analyses

SENATE JUDICIARY COMMITTEE 7/11/2007html
COMMITTEE ANALYSIS 6/20/2007html
ASSEMBLY THIRD READING 5/23/2007html
ASSEMBLY THIRD READING 5/9/2007html
ASSEMBLY COMMITTEE ON HEALTH 4/30/2007html

Votes

SEN. JUD. - 7/10/2007 (Y:2 N:2 A:1)html
SEN. JUD. - 7/10/2007 (Y:5 N:0 A:0)html
SEN. HEALTH - 6/20/2007 (Y:6 N:2 A:3)html
ASM. FLOOR - 5/24/2007 (Y:70 N:6 A:3)html
ASM. HEALTH - 5/1/2007 (Y:15 N:0 A:2)html

Affecting Same Code

People who track *AB 1587* also track:

88%	SB 840	Single-payer health care coverage.
87%	AB 8	Health care.
85%	AB 10	Children's Hospital Bond Act of 2008.
83%	SB 48	Community development: healthy food choices.

80% AB 1 Health care coverage.

Governor Message

Attachments/Links

Create new attachment/link new

AMENDED IN SENATE AUGUST 20, 2007

AMENDED IN SENATE JULY 19, 2007

AMENDED IN SENATE JULY 16, 2007

AMENDED IN SENATE JUNE 27, 2007

AMENDED IN ASSEMBLY MAY 21, 2007

AMENDED IN ASSEMBLY MAY 8, 2007

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 1587

Introduced by Assembly Member De La Torre
~~(Principal coauthor: Senator Lowenthal)~~

February 23, 2007

~~An act to relating to recall elections, and declaring the urgency thereof, to take effect immediately.~~ *An act to amend Section 56.05 of the Civil Code, relating to personal information.*

LEGISLATIVE COUNSEL'S DIGEST

AB 1587, as amended, De La Torre. ~~Recall elections: City of Lynwood.~~ *Personal information: pharmacy.*

The Confidentiality of Medical Information Act prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, using for marketing, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, unless a specified exception applies. That law excludes from the definition of marketing communications that are for a specified descriptive purpose, that are tailored to the circumstances of a

particular individual, or for which the communicator does not receive remuneration from a 3rd party, as specified.

This bill would additionally exclude from the definition of marketing a written communication or written message provided to a pharmacy patient by a pharmacist or pharmacy personnel that meets specified conditions.

~~Existing law provides the procedure for the recall of local government officers pursuant to a petition that is circulated for signatures and submitted by the proponents of the recall. It requires that when the city or county elections official is the officer sought to be recalled, the elections official's duties in connection with the recall process be performed by some other person designated by the applicable governing board.~~

~~This bill would state legislative findings that there exists a need for an experienced, objective, impartial, and professional entity to conduct any recall or special election that is held in the City of Lynwood in the County of Los Angeles during calendar years 2007 and 2008, and would state the intent of the Legislature in connection with this bill. It would require any recall or special election held in the City of Lynwood during the 2007 and 2008 calendar years to be administered by the Los Angeles County Registrar-Recorder, subject to approval by the Board of Supervisors.~~

~~This bill would require the City of Lynwood to pay the County of Los Angeles from the city treasury for any expenses authorized and necessarily incurred in conducting any recall or special election held in the City of Lynwood pursuant to this bill. It would provide a procedure under which the Controller would reallocate to the county amounts otherwise scheduled for distribution to the city from unrestricted funds or moneys, as specified.~~

~~The California Constitution provides that a local or special statute is invalid in any case if a general statute can be made applicable.~~

~~This bill would declare that, due to the unique circumstances pertaining to the City of Lynwood that the bill is intended to remedy, a general statute within the meaning of specified provisions of the California Constitution cannot be made applicable and a special statute is necessary.~~

~~This bill would declare that it is to take effect immediately as an urgency statute.~~

Vote: ~~2/3~~ *majority*. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 56.05 of the Civil Code is amended to read:

56.05. For purposes of this part:

(a) "Authorization" means permission granted in accordance with Section 56.11 or 56.21 for the disclosure of medical information.

(b) "Authorized recipient" means any person who is authorized to receive medical information pursuant to Section 56.10 or 56.20.

(c) "Contractor" means any person or entity that is a medical group, independent practice association, pharmaceutical benefits manager, or a medical service organization and is not a health care service plan or provider of health care. "Contractor" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code or pharmaceutical benefits managers licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(d) "Health care service plan" means any entity regulated pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(e) "Licensed health care professional" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act or the Chiropractic Initiative Act, or Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

(f) "Marketing" means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

"Marketing" does not include any of the following:

(1) Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication.

(2) Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network or health plan network of a

Knox-Keene licensed health plan to which the enrollees already subscribe; communications made to current enrollees solely for the purpose of describing if, and the extent to which, a product or service, or payment for a product or service, is provided by a provider, contractor, or plan or included in a plan of benefits of a Knox-Keene licensed health plan to which the enrollees already subscribe; or communications made to plan enrollees describing the availability of more cost-effective pharmaceuticals.

(3) Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment, as provided in Section 1399.901 of the Health and Safety Code, for a chronic and seriously debilitating or life-threatening condition as defined in subdivisions (d) and (e) of Section 1367.21 of the Health and Safety Code, if the health care provider, contractor, or health plan receives direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication, if all of the following apply:

(A) The individual receiving the communication is notified in the communication in typeface no smaller than 14-point type of the fact that the provider, contractor, or health plan has been remunerated and the source of the remuneration.

(B) The individual is provided the opportunity to opt out of receiving future remunerated communications.

(C) The communication contains instructions in typeface no smaller than 14-point type describing how the individual can opt out of receiving further communications by calling a toll-free number of the health care provider, contractor, or health plan making the remunerated communications. No further communication may be made to an individual who has opted out after 30 calendar days from the date the individual makes the opt out request.

(4) A written communication or written message provided to a pharmacy patient during a face-to-face interaction with a pharmacist or pharmacy personnel, in conjunction with dispensing a prescription drug, if all of the following apply:

(A) The communication does not involve the sale or transfer of medical information by the pharmacy to any other entity, or to the

pharmacy from another entity. Additionally, the communication is based only on medical information that has already been provided to, and maintained by, the pharmacist as necessary to the performance of the pharmacist's duties to fill prescriptions.

(B) The communication, either in whole or in part, assists the pharmacist or pharmacy personnel in meeting the goals of Section 601 of Public Law 104-180 with respect to the transmittal of useful information regarding a prescription drug dispensed to the patient.

(C) The content of the communication provides information regarding any of the following:

(i) The dispensed drug or a disease or health condition for which the dispensed drug is indicated.

(ii) Another treatment or therapy for a disease or health condition for which the dispensed drug is indicated if the content of the communication does not include any mention of, or negative statements regarding, the dispensed drug by proprietary or brand name and the treatment or therapy satisfies one or more of the following conditions:

(I) Is an adjunctive treatment or therapy that augments or assists the dispensed drug or therapy.

(II) Is a generic alternative for the dispensed drug.

(III) Has demonstrable benefits for the patient as compared to the dispensed drug based upon the prescribing information approved by the federal Food and Drug Administration (FDA), a finding or conclusion contained in the FDA approval package, or requirements or policies of the FDA. Any such claim may not be inconsistent with applicable requirements or policies of the FDA. These demonstrable benefits may include being more effective, having fewer or less serious side effects, or offering more convenient dosing.

(iii) A drug dispensed to the patient during the preceding year or a disease or health condition for which that drug is indicated.

(iv) General information about a health condition for which the patient's disease or health condition puts the patient at risk and that, if left untreated, may result in worsening of the health, symptoms, or daily functioning of the patient.

(v) General information about a health condition for which the patient may be at risk given the age or gender of the patient and that, if left untreated, may result in worsening of the health, symptoms, or daily functioning of the patient.

(vi) The information described in clauses (iii) to (v), inclusive, shall not include any mention, by the proprietary name, brand name, or generic name, of a specific drug or other product, treatment, therapy, or service, other than the dispensed drug or a drug dispensed to the patient during the preceding year.

(D) The pharmacist is available upon request of the patient to answer questions regarding the communication and the communication notifies the patient that he or she should consult a health care provider.

(E) If the communication is paid for, in whole or in part, by a manufacturer, distributor, or provider of a health care product or service, other than the pharmacy or a business associate of the pharmacy, the communication shall comply with all of the following:

(i) The communication shall, in a clear written statement placed in a clear and conspicuous location, disclose the source of the sponsorship in a typeface no smaller than 14-point type.

(ii) If the communication is related to information referenced in clause (i) , (ii), or (iii) of subparagraph (C) and mentions a prescription drug or other product, treatment, therapy, or service, other than the dispensed prescription drug, by its proprietary name, brand name, or generic name, the communication shall also contain the words "paid advertisement" in a typeface no smaller than 14-point type at the top of each sponsored message.

(iii) If a sponsored message is printed on more than one page of a communication, the statement required by clause (ii) shall appear on each page on which the sponsored message appears.

(iv) If a sponsored message is printed on more than one panel of the same page of a communication, the statement required by clause (ii) shall appear on each panel on which the sponsored message appears.

(v) If the communication is related to information referenced in clause (i), (ii), or (iii) of subparagraph (C) and mentions a prescription or other product, treatment, therapy, or service, other than the dispensed prescription drug, by its proprietary name, brand name, or generic name, the communication shall also contain the words "results may vary—consult your doctor."

(F) The communication contains instructions in a typeface no smaller than 14-point type describing how the patient can opt out of the portion of a pharmacy's communication that is paid for by

a manufacturer, distributor, or provider of a health care product or service by calling a toll-free number. No further sponsored message from the pharmacy may be made to an individual who has opted out after 30 calendar days from the date the individual makes the opt out request.

(G) A majority of the printed space of the entire communication delivered to the patient in the pharmacy is used for purposes other than a sponsored message that is subject to clause (ii) of subparagraph (E).

(H) Compliance with any provision in this paragraph shall not necessarily render any communication as truthful, not misleading, fairly balanced, or adequately substantiated, within the meaning of any applicable federal or state law, if that communication is otherwise false, misleading, lacking in fair balance, or not adequately substantiated.

(g) "Medical information" means any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment. "Individually identifiable" means that the medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity.

(h) "Patient" means any natural person, whether or not still living, who received health care services from a provider of health care and to whom medical information pertains.

(i) "Pharmaceutical company" means any company or business, or an agent or representative thereof, that manufactures, sells, or distributes pharmaceuticals, medications, or prescription drugs. "Pharmaceutical company" does not include a pharmaceutical benefits manager, as included in subdivision (c), or a provider of health care.

(j) "Provider of health care" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act;

any person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code; any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code. "Provider of health care" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code.

~~SECTION 1. The Legislature finds and declares that there exists a need for an experienced, objective, impartial, and professional entity to conduct any recall or special election that is held in the City of Lynwood in the County of Los Angeles during the 2007 and 2008 calendar years. It is the intent of the Legislature in enacting this statute to ensure the integrity, efficiency, and lawful conduct of recall and special elections in the City of Lynwood, to avoid real bias or the perception of bias or impropriety, and to strengthen the public's confidence in the fair and free operation of the election process and the reporting of election results.~~

~~SEC. 2. Any recall or special election in the City of Lynwood held during the 2007 and 2008 calendar years shall be administered, for all purposes, by the Los Angeles County Registrar-Recorder upon approval by the Board of Supervisors of the County of Los Angeles.~~

~~SEC. 3. (a) The City of Lynwood shall pay from its city treasury for all expenses authorized and necessarily incurred in conducting any special or recall election held during the 2007 and 2008 calendar years. These expenses shall be paid to the County of Los Angeles to reimburse the county for the costs of conducting the special or recall election.~~

~~(b) If payment is not made in a timely manner, and after sufficient notice to the City of Lynwood, the Board of Supervisors of the County of Los Angeles may pass a resolution informing the Controller that some or all of the amount due is outstanding.~~

~~(c) Following receipt of the resolution, the Controller shall deduct from apportionments scheduled for periodic distribution to the City of Lynwood, from any unrestricted funds or moneys, the outstanding balance owed and instead pay the amount to the County of Los Angeles.~~

~~SEC. 4. The Legislature finds and declares that because of the unique circumstances of the City of Lynwood, relating to the conduct of elections, a statute of general applicability cannot be~~

~~enacted within the meaning of subdivision (b) of Section 16 of Article IV of the California Constitution. Therefore, it is necessary to enact a special statute applicable only to the City of Lynwood.~~

~~SEC. 5. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:~~

~~In order to ensure that recall elections in the City of Lynwood proceed in a timely fashion in accordance with state law, and to preserve the public's confidence in the electoral process and the voters' reserve power to recall elected officials, it is necessary that this act take effect immediately.~~

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1947

VERSION: As Amended March 24, 2008
Introduced: February 13, 2008

AUTHOR: Emmerson

SPONSOR: California Society of Health-System Pharmacists

RECOMMENDED POSITION:

SUBJECT: Pharmacy technicians

EXISTING LAW:

1. Provides for the licensure and regulation of pharmacy technicians by the Board of Pharmacy.
2. Authorizes the board to issue a pharmacy technician license to an individual who is a high school graduate or who possesses a GED and has either obtained a specified associate's degree, completed a specified course of training, graduated from a specified school of pharmacy, or is certified by the Pharmacy Technician Certification Board.

THIS BILL WOULD:

1. Authorize the board to issue a pharmacy technician license to an individual if that individual is a high school graduate or who possesses a GED, is certified by the Pharmacy Technician Certification Board or passes a pharmacy technician examination approved by the board, and has either a obtained a specified associate's degree, completed a specified courses of training, or graduated from a specified school of pharmacy.
2. The bill specifies that these requirements shall only apply to pharmacy technicians issued an initial license on and after January 1, 2009.
3. Require a pharmacy technician to successfully complete 20 hours of approved courses of continuing pharmacy education during the 2-years preceding an application for renewal.
4. Specify the form and subject matter content for these continuing education courses.
5. Provide that a pharmacy technician license that is not renewed within 3-years after expiration may not be renewed and shall be canceled at the end of a 3-year period.

AUTHOR'S INTENT

This bill is intended to amend section 4202 and 4231 of the Business and Professions Code and add sections 4230, 4230.5 and 4410 to the Business and Professions Code as it relates the licensure requirements for pharmacy technicians and conditions for renewal and cancellation of a pharmacy technician license.

FISCAL IMPACT:

The board anticipates the addition of one staff person to audit continuing education and issue citations and fines for violations.

SUPPORT and OPPOSITION:

COMMENTS:

At this time, the sponsor, CSHP is not moving the bill.

HISTORY:

Dates	Actions
03/25/08	Mar. 25 Re-referred to Com. on B. & P.
03/24/08	Mar. 24 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
02/28/08	Feb. 28 Referred to Com. on B. & P.
02/14/08	Feb. 14 From printer. May be heard in committee March 15.
02/13/08	Feb. 13 Read first time. To print.

AMENDED IN ASSEMBLY MARCH 24, 2008

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 1947

Introduced by Assembly Member Emmerson

February 13, 2008

An act to amend ~~Section 4202~~ *Sections 4202 and 4231* of, and to add ~~Section 4231.5~~ *Sections 4230, 4230.5, and 4410* to, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 1947, as amended, Emmerson. Pharmacy technicians.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacy technicians by the California State Board of Pharmacy. Existing law authorizes the board to adopt rules and regulations necessary for the protection of the public. Existing law authorizes the board to issue a pharmacy technician license to an individual if that individual is a high school graduate or possesses a general educational development certificate equivalent and has either obtained a specified associate's degree, completed a specified course of training, graduated from a specified school of pharmacy, or is certified by the Pharmacy Technician Certification Board. Existing law prohibits the board from renewing a pharmacist license, after the first renewal, unless the applicant submits satisfactory proof that he or she has successfully completed 30 hours of approved courses of continuing pharmacy education during the 2 years preceding the application for renewal.

This bill would instead authorize the board to issue a pharmacy technician license to an individual if that individual is a high school graduate or possesses a general educational development certificate

equivalent, is certified by the Pharmacy Technician Certification Board or passes ~~a specified board-approved~~ *pharmacy technician* examination *approved by the board*, and has either obtained a specified associate's degree, completed a specified course of training, or graduated from a specified school of pharmacy. *The bill would specify that these requirements shall only apply to pharmacy technicians issued on initial license on and after January 1, 2009.* The bill would also prohibit the board from renewing a pharmacist technician license, after the first renewal, unless the applicant submits satisfactory proof that he or she has successfully completed 20 hours of approved courses of continuing pharmacy education during the 2 years preceding the application for renewal. ~~The bill would require the board to adopt regulations with respect to this continuing education requirement.~~ *The bill would specify the form and subject matter content for these courses. The bill would provide that a pharmacy technician license that is not renewed within 3 years after expiration may not be renewed and shall be canceled at the end of the 3-year period. The bill would make conforming changes.*

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 4202 of the Business and Professions Code is amended to read:

4202. (a) The board may issue a pharmacy technician license to an individual if he or she is a high school graduate or possesses a general educational development certificate equivalent, is certified by the Pharmacy Technician Certification Board or passes ~~a board-approved examination that is based on psychometrically sound principles~~ *a pharmacy technician examination approved by the board*, and meets any one of the following requirements:

(1) Has obtained an associate's degree in pharmacy technology.

(2) Has completed a course of training specified by the board.

(3) Has graduated from a school of pharmacy recognized by the board.

(b) The board shall adopt regulations pursuant to this section for the licensure of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of subdivision (a). Proof of the qualifications of any applicant for licensure as a

pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.

(c) The board shall conduct a criminal background check of an applicant to determine if the applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(d) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.

(e) Once licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician license shall be returned to the board within 15 days.

(f) An examination for certification of a pharmacy technician or a pharmacy technician examination approved by the board shall be subject to Section 139.

(g) The requirement in subdivision (a) of certification by the Pharmacy Technician Certification Board or passing a pharmacy technician examination approved by the board shall only apply to pharmacy technicians issued an initial license on and after January 1, 2009.

SEC. 2. Section ~~4231.5~~ *4230* is added to the Business and Professions Code, to read:

~~4231.5.~~

4230. (a) The board shall not renew a pharmacy technician license unless the applicant submits proof satisfactory to the board that he or she has successfully completed 20 hours of approved courses of continuing pharmacy *technician* education *as described in Section 4230.5* during the two years preceding the application for renewal.

(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal of a pharmacy technician license.

(c) If an applicant for renewal of a pharmacy technician license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed 20 hours of continuing pharmacy education, the board shall not renew the license and shall issue the applicant an inactive pharmacy technician license. A licensee with an inactive pharmacy technician license issued pursuant to this section may obtain an active pharmacy technician license by paying the renewal

fees due and submitting satisfactory proof to the board that the licensee has completed 20 hours of continuing pharmacy education.

~~(d) The board shall adopt regulations to implement this section.~~

SEC. 3. Section 4230.5 is added to the Business and Professions Code, to read:

4230.5. (a) The courses shall be in the form of studies, institutes, seminars, lectures, conferences, workshops, extension studies, correspondence courses, and other similar methods of conveying continuing professional pharmacy technician education.

(b) The subject matter may be pertinent to the socioeconomic and legal aspects of health care, the properties and actions of drugs and dosage forms, and the etiology, characteristics, and therapeutics of the disease state.

(c) The subject matter of the courses may also include, but shall not be limited to, the following: pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, pharmacy jurisprudence, public health and communicable diseases, professional practice management, anatomy, and histology.

SEC. 4. Section 4231 of the Business and Professions Code is amended to read:

4231. (a) The board shall not renew a pharmacist license unless the applicant submits proof satisfactory to the board that he or she has successfully completed 30 hours of approved courses of continuing pharmacy education *as described in Section 4232* during the two years preceding the application for renewal.

(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal of a pharmacist license.

(c) If an applicant for renewal of a pharmacist license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed 30 hours of continuing pharmacy education, the board shall not renew the license and shall issue the applicant an inactive pharmacist license. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.

SEC. 5. Section 4410 is added to the Business and Professions Code, to read:

4410. Any pharmacy technician license that is not renewed within three years following its expiration may not be renewed and shall be canceled by operation of law at the end of the three-year period.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2516 VERSION: Introduced: February 21, 2008

AUTHOR: Mendoza SPONSOR: Senior Legislature

RECOMMENDED POSITION:

SUBJECT: Prescriptions: electronic Transmission

EXISTING LAW:

1. Regulates the dispensing by prescription of dangerous drugs and dangerous devices.
2. Authorizes a prescriber or his or her authorized agent to electronically transmit a prescription to a pharmacy, subject o certain exceptions.

THIS BILL WOULD:

1. Commencing January 1, 2010, require a prescriber to ensure that any prescription issued or made by him or her be electronically transmitted to the patient's pharmacy of choice, except at specified.
2. Provide that violation of these provisions is not a crime.

AUTHOR'S INTENT

To authorize a prescriber to e-mail a prescription to the pharmacy of a patient's choice to allow for a faster, more efficient and cost savings method of dispensing prescriptions to consumers.

FISCAL IMPACT:

The board does not anticipate any substantial fiscal impact to its operations.

COMMENTS:

HISTORY:

Dates	Actions
03/06/08	Mar. 6 Referred to Com. on B. & P.
02/23/08	Feb. 23 From printer. May be heard in committee March 24.
02/21/08	Feb. 21 Read first time. To print.

ASSEMBLY BILL No. 2516

Introduced by Assembly Member Mendoza

February 21, 2008

An act to add Section 4072.5 to the Business and Professions Code, relating to prescriptions.

LEGISLATIVE COUNSEL'S DIGEST

AB 2516, as introduced, Mendoza. Prescriptions: electronic transmission.

The Pharmacy Law regulates, among other matters, the dispensing by prescription of dangerous drugs and dangerous devices, and sets forth specified requirements for prescriptions. Existing law authorizes a prescriber or his or her authorized agent to electronically transmit a prescription to a pharmacist, subject to certain exceptions. A knowing violation of the Pharmacy Law is a crime.

This bill would, commencing January 1, 2010, require a prescriber to ensure that any prescription issued or made by him or her be electronically transmitted to the patient's pharmacy of choice, except as specified. The bill would provide that a violation of these provisions is not a crime.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 4072.5 is added to the Business and Professions Code, to read:

4072.5. (a) A prescriber shall ensure that any prescription issued or made by him or her be electronically transmitted to the patient's pharmacy of choice, except for any of the following:

(1) A prescription required by federal law to be transmitted in another manner.

(2) A prescription that is prevented from being transmitted electronically at the time of issuance by an emergency or unexpected technical problem.

(3) An order meeting the requirements of Section 4019 if the prescribed drug is to be administered at the hospital.

(b) Notwithstanding any other provisions of law, a violation of this section shall not be a crime.

(c) This section shall become operative on January 1, 2010.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2643 Introduced: February 22, 2008

AUTHOR: Cook SPONSOR: Medical Oncology Association of California and Association of Northern California Oncologists.

RECOMMENDED POSITION:

SUBJECT: Drugs and Devices

EXISTING LAW:

References the United States Pharmacopoeia in various health care provisions.

THIS BILL WOULD:

Replace the references of the United States Pharmacopoeia in the above with the DrugPoints.

AUTHOR'S INTENT

This bill is intended to make a technical amendment to various sections of the Business and Professions codes as it relates to Pharmacy Law, sections of the Health and Safety Code, the Insurance Code, the Penal Code, Public Resources Code, and the Welfare and Institutions Code.

FISCAL IMPACT:

The board does not anticipate any substantial fiscal impact to its operations.

COMMENTS: In discussion with the author's office, this bill is not moving forward at this time.

HISTORY:

Dates	Actions
03/06/08	Mar. 6 Referred to Com. on B. & P.
02/23/08	Feb. 23 From printer. May be heard in committee March 24.
02/21/08	Feb. 21 Read first time. To print.

ASSEMBLY BILL No. 2643

Introduced by Assembly Member Cook

February 22, 2008

An act to amend Sections 13, 4025, 4053, and 4342 of the Business and Professions Code, to amend Sections 1367.21, 1370.4, 11014, 109920, 109985, 111225, 111235, 111656.4, and 150204 of the Health and Safety Code, to amend Sections 10123.195 and 10145.3 of the Insurance Code, to amend Section 383 of the Penal Code, to amend Section 47121 of the Public Resources Code, and to amend Sections 14105.43 and 14133.2 of the Welfare and Institutions Code, relating to drugs and devices.

LEGISLATIVE COUNSEL'S DIGEST

AB 2643, as introduced, Cook. Drugs and devices.

Existing law references the United States Pharmacopoeia in various health care provisions.

This bill would replace the references to the United States Pharmacopoeia in the above-described provisions with the DrugPoints.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 13 of the Business and Professions Code is amended to read:

13. The term "materia medica" as used in this code or in any initiative act referred to in this code, means those substances listed in the ~~official United States Pharmacopoeia~~ *DrugPoints*, the official

Homeopathic Pharmacopoeia of the United States, the official United States Dispensatory, New and Nonofficial Remedies, or the National Formulary, or any supplement thereof, except substances covered by subdivision (a) of Section 4052 and Section 4057 of this code.

SEC. 2. Section 4025 of the Business and Professions Code is amended to read:

4025. "Drug" means any of the following:

(a) Articles recognized in the ~~official United States Pharmacopoeia~~ *DrugPoints*, official National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement of any of them.

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

(c) Articles (other than food) intended to affect the structure or any function of the body of humans or other animals.

(d) Articles intended for use as a component of any article specified in subdivision (a), (b), or (c).

SEC. 3. Section 4053 of the Business and Professions Code is amended to read:

4053. (a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.

(b) An individual may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development equivalent.

(2) He or she shall have a minimum of one year of paid work experience, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the ~~United States Pharmacopoeia~~ *DrugPoints* standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.

(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.

(e) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

SEC. 4. Section 4342 of the Business and Professions Code is amended to read:

4342. (a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the ~~United States Pharmacopoeia~~ *DrugPoints* or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321.

SEC. 5. Section 1367.21 of the Health and Safety Code is amended to read:

1367.21. (a) No health care service plan contract which covers prescription drug benefits shall be issued, amended, delivered, or renewed in this state if the plan limits or excludes coverage for a drug on the basis that the drug is prescribed for a use that is different from the use for which that drug has been approved for marketing by the federal Food and Drug Administration (FDA), provided that all of the following conditions have been met:

(1) The drug is approved by the FDA.

(2) (A) The drug is prescribed by a participating licensed health care professional for the treatment of a life-threatening condition; or

(B) The drug is prescribed by a participating licensed health care professional for the treatment of a chronic and seriously debilitating condition, the drug is medically necessary to treat that condition, and the drug is on the plan formulary. If the drug is not on the plan formulary, the participating subscriber's request shall be considered pursuant to the process required by Section 1367.24.

(3) The drug has been recognized for treatment of that condition by one of the following:

(A) The American Medical Association Drug Evaluations.

(B) The American Hospital Formulary Service Drug Information.

(C) The ~~United States Pharmacopoeia Dispensing Information, Volume 1, "Drug Information for the Health Care Professional."~~ *DrugPoints.*

(D) Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

(b) It shall be the responsibility of the participating prescriber to submit to the plan documentation supporting compliance with the requirements of subdivision (a), if requested by the plan.

(c) Any coverage required by this section shall also include medically necessary services associated with the administration of a drug, subject to the conditions of the contract.

(d) For purposes of this section, "life-threatening" means either or both of the following:

(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(e) For purposes of this section, "chronic and seriously debilitating" means diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.

(f) The provision of drugs and services when required by this section shall not, in itself, give rise to liability on the part of the plan.

(g) Nothing in this section shall be construed to prohibit the use of a formulary, copayment, technology assessment panel, or similar mechanism as a means for appropriately controlling the utilization of a drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA.

(h) If a plan denies coverage pursuant to this section on the basis that its use is experimental or investigational, that decision is subject to review under Section 1370.4.

(i) Health care service plan contracts for the delivery of Medi-Cal services under the Waxman-Duffy Prepaid Health Plan Act (Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code) are exempt from the requirements of this section.

SEC. 6. Section 1370.4 of the Health and Safety Code is amended to read:

1370.4. (a) Every health care service plan shall provide an external, independent review process to examine the plan's coverage decisions regarding experimental or investigational therapies for individual enrollees who meet all of the following criteria:

(1) (A) The enrollee has a life-threatening or seriously debilitating condition.

(B) For purposes of this section, "life-threatening" means either or both of the following:

(i) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(ii) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(C) For purposes of this section, "seriously debilitating" means diseases or conditions that cause major irreversible morbidity.

(2) The enrollee's physician certifies that the enrollee has a condition, as defined in paragraph (1), for which standard therapies have not been effective in improving the condition of the enrollee, for which standard therapies would not be medically appropriate for the enrollee, or for which there is no more beneficial standard therapy covered by the plan than the therapy proposed pursuant to paragraph (3).

(3) Either (A) the enrollee's physician, who is under contract with or employed by the plan, has recommended a drug, device, procedure or other therapy that the physician certifies in writing is likely to be more beneficial to the enrollee than any available standard therapies, or (B) the enrollee, or the enrollee's physician who is a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the enrollee's condition, has requested a therapy that, based on two documents from the medical and scientific evidence, as defined in subdivision (d), is likely to be more beneficial for the enrollee than any available standard therapy. The physician certification pursuant to this subdivision shall include a statement of the evidence relied upon by the physician in certifying his or her recommendation. Nothing in this subdivision shall be construed to require the plan to pay for the services of a nonparticipating physician provided pursuant to this subdivision, that are not otherwise covered pursuant to the plan contact.

(4) The enrollee has been denied coverage by the plan for a drug, device, procedure, or other therapy recommended or requested pursuant to paragraph (3).

(5) The specific drug, device, procedure, or other therapy recommended pursuant to paragraph (3) would be a covered service, except for the plan's determination that the therapy is experimental or investigational.

(b) The plan's decision to delay, deny, or modify experimental or investigational therapies shall be subject to the independent medical review process under Article 5.55 (commencing with Section 1374.30) except that, in lieu of the information specified in subdivision (b) of Section 1374.33, an independent medical reviewer shall base his or her determination on relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence defined in subdivision (d).

(c) The independent medical review process shall also meet the following criteria:

(1) The plan shall notify eligible enrollees in writing of the opportunity to request the external independent review within five business days of the decision to deny coverage.

(2) If the enrollee's physician determines that the proposed therapy would be significantly less effective if not promptly initiated, the analyses and recommendations of the experts on the panel shall be rendered within seven days of the request for expedited review. At the request of the expert, the deadline shall be extended by up to three days for a delay in providing the documents required. The timeframes specified in this paragraph shall be in addition to any otherwise applicable timeframes contained in subdivision (c) of Section 1374.33.

(3) Each expert's analysis and recommendation shall be in written form and state the reasons the requested therapy is or is not likely to be more beneficial for the enrollee than any available standard therapy, and the reasons that the expert recommends that the therapy should or should not be provided by the plan, citing the enrollee's specific medical condition, the relevant documents provided, and the relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence as defined in subdivision (d), to support the expert's recommendation.

(4) Coverage for the services required under this section shall be provided subject to the terms and conditions generally applicable to other benefits under the plan contract.

(d) For the purposes of subdivision (b), "medical and scientific evidence" means the following sources:

(1) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

(2) Peer-reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline, and MEDLARS data base Health Services Technology Assessment Research (HSTAR).

(3) Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act.

(4) The following standard reference compendia: The American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluation, the American Dental Association Accepted Dental Therapeutics, and the ~~United States Pharmacopoeia-Drug Information~~ *DrugPoints*.

(5) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including the Federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.

(6) Peer-reviewed abstracts accepted for presentation at major medical association meetings.

(e) The independent review process established by this section shall be required on and after January 1, 2001.

SEC. 7. Section 11014 of the Health and Safety Code is amended to read:

11014. "Drug" means (a) substances recognized as drugs in the official ~~United States Pharmacopoeia~~ *DrugPoints*, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (b) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (c) substances (other than food) intended to affect the structure or any function of the body of man or animals; and (d) substances intended for use as a component of any article specified in subdivision (a), (b), or (c) of this section. It does not include devices or their components, parts, or accessories.

SEC. 8. Section 109920 of the Health and Safety Code is amended to read:

109920. "Device" means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is any of the following:

(a) Recognized in the official National Formulary or the ~~United States Pharmacopoeia~~ *DrugPoints*, or any supplement to them.

(b) Intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease in humans or any other animal.

(c) Intended to affect the structure or any function of the body of humans or any other animal and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and that is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

SEC. 9. Section 109985 of the Health and Safety Code is amended to read:

109985. "Official compendium" means the latest edition of the ~~United States Pharmacopoeia~~ *DrugPoints*, the latest edition of the Homeopathic Pharmacopoeia of the United States, or the latest edition of the National Formulary, or any supplement to any of these.

SEC. 10. Section 111225 of the Health and Safety Code is amended to read:

111225. As used in this chapter, with respect to a drug or drug ingredient, "established name" means either of the following:

(a) The name designated pursuant to Section 508 of the federal act (21 U.S.C. Sec. 358).

(b) If there is no such name and the drug or ingredient is an article recognized in an official compendium, then the official title in the compendium is the established name.

If neither subdivision (a) or (b) of this section applies, the common or usual name, if any, of the drug or of the ingredient is the established name. When an article is recognized in the ~~United States Pharmacopoeia~~ *DrugPoints* and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the ~~United States Pharmacopoeia~~ *DrugPoints* shall apply unless it is labeled and offered for sale as a homeopathic drug. If it is labeled and offered for sale as a homeopathic drug, the official title used in the Homeopathic Pharmacopoeia shall apply.

SEC. 11. Section 111235 of the Health and Safety Code is amended to read:

111235. Whenever a drug is recognized in both the ~~United States Pharmacopoeia~~ *DrugPoints* and the Homeopathic

Pharmacopoeia of the United States, it shall be subject to the requirements of the ~~United States Pharmacopoeia~~ *DrugPoints* unless it is labeled and offered for sale as a homeopathic drug. If it is labeled and offered for sale as a homeopathic drug, it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the ~~United States Pharmacopoeia~~ *DrugPoints*.

SEC. 12. Section 111656.4 of the Health and Safety Code is amended to read:

111656.4. Section 4051 of the Business and Professions Code shall not prohibit a home medical device retail facility from selling or dispensing prescription devices if the department finds that sufficient qualified supervision is employed by the home medical device retail facility to adequately safeguard and protect the public health. Each person applying to the department for this exemption shall meet the following requirements to obtain and maintain the exemption:

(a) A licensed pharmacist or an exemptee who meets the requirements set forth in paragraphs (1) to (5), inclusive, and whose license of exemption is currently valid, shall be in charge of the home medical device retail facility.

(1) He or she shall be a high school graduate or possess a general education development equivalent.

(2) He or she shall have a minimum of one year of paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices.

(3) He or she shall complete a training program that addresses each of the following subjects that are applicable to his or her duties:

(A) Knowledge and understanding of state and federal laws relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of state and federal laws relating the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the ~~United States Pharmacopoeia~~ *DrugPoints* standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding relating to the safe storage and handling of home medical devices.

(F) Knowledge and understanding of prescription terminology, abbreviations, and format.

(4) The department may, by regulation, require training programs that include additional material.

(5) The department shall not issue an exemptee a license until the applicant provides proof of completion of the required training that the department determines is adequate to fulfill these requirements.

(b) The licensed pharmacist or exemptee shall be on the premises at all times that prescription devices are available for sale or fitting unless the prescription devices are stored separately from other merchandise and are under the exclusive control of the licensed pharmacist or exemptee. A licensed pharmacist or an exemptee need not be present in the warehouse facility of a home medical device retail facility unless the department establishes that requirement by regulation based upon the need to protect the public.

(c) The department may require an exemptee to complete a designated number of hours of coursework in department-approved courses of home health education in the disposition of any disciplinary action taken against the exemptee.

(d) Each premises maintained by a home medical device retail facility shall have a license issued by the department and shall have a licensed pharmacist or exemptee on the premises if prescription devices are furnished, sold, or dispensed.

(e) A home medical device retail facility may establish locked storage (a lock box or locked area) for emergency or after working hours furnishing of prescription devices. Locked storage may be installed or placed in a service vehicle of the home medical device retail facility for emergency or after hours service to patients having prescriptions for prescription devices.

(f) The department may by regulation authorize a licensed pharmacist or exemptee to direct an employee of the home medical device retail facility who operates the service vehicle equipped with locked storage described in subdivision (e) to deliver a prescription device from the locked storage to patients having prescriptions for prescription devices. These regulations shall establish inventory requirements for the locked storage by a licensed pharmacist or exemptee to take place shortly after a

prescription device has been delivered from the locked storage to a patient.

SEC. 13. Section 150204 of the Health and Safety Code is amended to read:

150204. (a) A county may establish, by ordinance, a repository and distribution program for purposes of this division. Only pharmacies that are county-owned or that contract with the county pursuant to this division may participate in this program to dispense medication donated to the drug repository and distribution program.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Developing a formulary of medications appropriate for the repository and distribution program.

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a county-owned or county-contracted, licensed pharmacy.

(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.

(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:

(1) The medication shall not be a controlled substance.

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the ~~United States Pharmacopoeia (USP)~~ *DrugPoints* or the product manufacturer.

(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a skilled nursing facility, shall have been under the control of staff of the skilled nursing facility.

(d) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet ~~USP~~ *DrugPoints* standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates

are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program.

(e) A pharmacist shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.

(f) A pharmacist shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

(g) Medication that is donated to the repository and distribution program shall be handled in any of the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor.

(h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed under this program and shall be either destroyed or returned to a reverse distributor. This medication shall not be sold, dispensed, or otherwise transferred to any other entity.

(i) Medication donated to the repository and distribution program shall be maintained in the donated packaging units until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed.

(j) Medication donated to the repository and distribution program shall be segregated from the pharmacy's other drug stock by physical means, for purposes including, but not limited to, inventory, accounting, and inspection.

(k) The pharmacy shall keep complete records of the acquisition and disposition of medication donated to and dispensed under the repository and distribution program. These records shall be kept separate from the pharmacy's other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.

(*l*) Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health and Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at their appropriate temperatures and in accordance with ~~USP~~ *DrugPoint* standards and the Pharmacy Law.

(n) Notwithstanding any other provision of law, a participating county-owned or county-contracted pharmacy shall follow the same procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.

SEC. 14. Section 10123.195 of the Insurance Code is amended to read:

10123.195. (a) No group or individual disability insurance policy issued, delivered, or renewed in this state or certificate of group disability insurance issued, delivered, or renewed in this state pursuant to a master group policy issued, delivered, or renewed in another state that, as a provision of hospital, medical, or surgical services, directly or indirectly covers prescription drugs shall limit or exclude coverage for a drug on the basis that the drug is prescribed for a use that is different from the use for which that drug has been approved for marketing by the federal Food and Drug Administration (FDA), provided that all of the following conditions have been met:

(1) The drug is approved by the FDA.

(2) (A) The drug is prescribed by a contracting licensed health care professional for the treatment of a life-threatening condition; or

(B) The drug is prescribed by a contracting licensed health care professional for the treatment of a chronic and seriously debilitating condition, the drug is medically necessary to treat that condition, and the drug is on the insurer's formulary, if any.

(3) The drug has been recognized for treatment of that condition by one of the following:

(A) The American Medical Association Drug Evaluations.

(B) The American Hospital Formulary Service Drug Information.

(C) The ~~United States Pharmacopoeia Dispensing Information, Volume 1, "Drug Information for the Health Care Professional."~~ *DrugPoints.*

(D) Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

(b) It shall be the responsibility of the contracting prescriber to submit to the insurer documentation supporting compliance with the requirements of subdivision (a), if requested by the insurer.

(c) Any coverage required by this section shall also include medically necessary services associated with the administration of a drug subject to the conditions of the contract.

(d) For purposes of this section, "life-threatening" means either or both of the following:

(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(e) For purposes of this section, "chronic and seriously debilitating" means diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.

(f) The provision of drugs and services when required by this section shall not, in itself, give rise to liability on the part of the insurer.

(g) This section shall not apply to a policy of disability insurance that covers hospital, medical, or surgical expenses which is issued outside of California to an employer whose principal place of business is located outside of California.

(h) Nothing in this section shall be construed to prohibit the use of a formulary, copayment, technology assessment panel, or similar mechanism as a means for appropriately controlling the utilization of a drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA.

(i) If an insurer denies coverage pursuant to this section on the basis that its use is experimental or investigational, that decision is subject to review under the Independent Medical Review System of Article 3.5 (commencing with Section 10169).

(j) This section is not applicable to vision-only, dental-only, Medicare or Champus supplement, disability income, long-term care, accident-only, specified disease or hospital confinement indemnity insurance.

SEC. 15. Section 10145.3 of the Insurance Code is amended to read:

10145.3. (a) Every disability insurer that covers hospital, medical, or surgical benefits shall provide an external, independent review process to examine the insurer's coverage decisions regarding experimental or investigational therapies for individual insureds who meet all of the following criteria:

(1) (A) The insured has a life-threatening or seriously debilitating condition.

(B) For purposes of this section, "life-threatening" means either or both of the following:

(i) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(ii) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(C) For purposes of this section, "seriously debilitating" means diseases or conditions that cause major irreversible morbidity.

(2) The insured's physician certifies that the insured has a condition, as defined in paragraph (1), for which standard therapies have not been effective in improving the condition of the insured, for which standard therapies would not be medically appropriate for the insured, or for which there is no more beneficial standard therapy covered by the insurer than the therapy proposed pursuant to paragraph (3).

(3) Either (A) the insured's contracting physician has recommended a drug, device, procedure, or other therapy that the physician certifies in writing is likely to be more beneficial to the insured than any available standard therapies, or (B) the insured, or the insured's physician who is a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the insured's condition, has requested a therapy that, based on two documents from the medical and scientific

evidence, as defined in subdivision (d), is likely to be more beneficial for the insured than any available standard therapy. The physician certification pursuant to this subdivision shall include a statement of the evidence relied upon by the physician in certifying his or her recommendation. Nothing in this subdivision shall be construed to require the insurer to pay for the services of a noncontracting physician, provided pursuant to this subdivision, that are not otherwise covered pursuant to the contract.

(4) The insured has been denied coverage by the insurer for a drug, device, procedure, or other therapy recommended or requested pursuant to paragraph (3), unless coverage for the specific therapy has been excluded by the insurer's contract.

(5) The specific drug, device, procedure, or other therapy recommended pursuant to paragraph (3) would be a covered service except for the insurer's determination that the therapy is experimental or under investigation.

(b) The insurer's decision to deny, delay, or modify experimental or investigational therapies shall be subject to the independent medical review process established under Article 3.5 (commencing with Section 10169) of Chapter 1 of Part 2 of Division 2, except that in lieu of the information specified in subdivision (b) of Section 10169.3, an independent medical reviewer shall base his or her determination on relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence defined in subdivision (d).

(c) The independent medical review process shall also meet the following criteria:

(1) The insurer shall notify eligible insureds in writing of the opportunity to request the external independent review within five business days of the decision to deny coverage.

(2) If the insured's physician determines that the proposed therapy would be significantly less effective if not promptly initiated, the analyses and recommendations of the experts on the panel shall be rendered within seven days of the request for expedited review. At the request of the expert, the deadline shall be extended by up to three days for a delay in providing the documents required. The timeframes specified in this paragraph shall be in addition to any otherwise applicable timeframes contained in subdivision (c) of Section 10169.3.

(3) Each expert's analysis and recommendation shall be in written form and state the reasons the requested therapy is or is not likely to be more beneficial for the insured than any available standard therapy, and the reasons that the expert recommends that the therapy should or should not be covered by the insurer, citing the insured's specific medical condition, the relevant documents, and the relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence as defined in subdivision (d), to support the expert's recommendation.

(4) Coverage for the services required under this section shall be provided subject to the terms and conditions generally applicable to other benefits under the contract.

(d) For the purposes of subdivision (b), "medical and scientific evidence" means the following sources:

(1) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

(2) Peer-reviewed literature, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), Medline and MEDLARS data base Health Services Technology Assessment Research (HSTAR).

(3) Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act.

(4) The following standard reference compendia: The American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluation, the American Dental Association Accepted Dental Therapeutics and ~~The United States Pharmacopoeia-Drug Information~~ *the DrugPoints*.

(5) Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including the Federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National

Institutes of Health for the purpose of evaluating the medical value of health services.

(6) Peer-reviewed abstracts accepted for presentation at major medical association meetings.

(e) The independent review process established by this section shall be required on and after January 1, 2001.

SEC. 16. Section 383 of the Penal Code is amended to read:

383. Every person who knowingly sells, or keeps or offers for sale, or otherwise disposes of any article of food, drink, drug, or medicine, knowing that the same is adulterated or has become tainted, decayed, spoiled, or otherwise unwholesome or unfit to be eaten or drunk, with intent to permit the same to be eaten or drunk, is guilty of a misdemeanor, and must be fined not exceeding one thousand dollars ($1,000), or imprisoned in the county jail not exceeding six months, or both, and may, in the discretion of the court, be adjudged to pay, in addition, all the necessary expenses, not exceeding one thousand dollars ($1,000), incurred in inspecting and analyzing ~~such~~ *these* articles. The term "drug," as used herein, includes all medicines for internal or external use, antiseptics, disinfectants, and cosmetics. The term "food," as used herein, includes all articles used for food or drink by man, whether simple, mixed, or compound. Any article is deemed to be adulterated within the meaning of this section:

(a) In case of drugs: (1) if, when sold under or by a name recognized in the ~~United States Pharmacopoeia~~ *DrugPoints*, it differs materially from the standard of strength, quality, or purity laid down therein; (2) if, when sold under or by a name not recognized in the ~~United States Pharmacopoeia~~ *DrugPoints*, but which is found in some other pharmacopoeia or other standard work on materia medica, it differs materially from the standard of strength, quality, or purity laid down in ~~such~~ *this* work; (3) if its strength, quality, or purity falls below the professed standard under which it is sold.

(b) In the case of food: (1) if any substance or substances have been mixed with it, so as to lower or depreciate, or injuriously affect its quality, strength, or purity; (2) if any inferior or cheaper substance or substances have been substituted wholly or in part for it; (3) if any valuable or necessary constituent or ingredient has been wholly or in part abstracted from it; (4) if it is an imitation of, or is sold under the name of, another article; (5) if it

consists wholly, or in part, of a diseased, decomposed, putrid, infected, tainted, or rotten animal or vegetable substance or article, whether manufactured or not; or in the case of milk, if it is the produce of a diseased animal; (6) if it is colored, coated, polished, or powdered, whereby damage or inferiority is concealed, or if by any means it is made to appear better or of greater value than it really is; (7) if it contains any added substance or ingredient which is poisonous or injurious to health.

SEC. 17. Section 47121 of the Public Resources Code is amended to read:

47121. For the purposes of this article, the following terms have the following meanings, unless the context clearly requires otherwise:

(a) "Consumer" means an individual purchaser or owner of a drug. "Consumer" does not include a business, corporation, limited partnership, or an entity involved in a wholesale transaction between a distributor and retailer.

(b) "Drug" means any of the following:

(1) Articles recognized in the ~~official United States Pharmacopoeia~~ *DrugPoints*, the official National Formulary, the official Homeopathic Pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias.

(2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

(3) Articles, excluding food, intended to affect the structure or function of the body of humans or other animals.

(4) Articles intended for use as a component of an article specified in paragraph (1), (2), or (3).

(c) "Participant" means any entity which the board deems appropriate for implementing and evaluating a model program and which chooses to participate, including, but not limited to, governmental entities, pharmacies, veterinarians, clinics, and other medical settings.

(d) "Sale" includes, but is not limited to, transactions conducted through sales outlets, catalogs, or the Internet, or any other similar electronic means, but does not include a sale that is a wholesale transaction with a distributor or retailer.

SEC. 18. Section 14105.43 of the Welfare and Institutions Code is amended to read:

14105.43. (a) (1) Notwithstanding other provisions of this chapter, any drug which is approved by the federal Food and Drug Administration for use in the treatment of acquired immune deficiency syndrome (AIDS) or an AIDS-related condition shall be deemed to be approved for addition to the Medi-Cal list of contract drugs only for the purpose of treating AIDS or an AIDS-related condition, for the period prior to the completion of the procedures established pursuant to Section 14105.33.

(2) (A) In addition to any drug that is deemed to be approved pursuant to paragraph (1), any drug that meets any of the following criteria shall be a Medi-Cal benefit, subject to utilization controls:

(i) Any vaccine to protect against human immunodeficiency virus (HIV) infection.

(ii) Any antiviral agent, immune modulator, or other agent to be administered to persons who have been infected with human immunodeficiency virus to counteract the effects of that infection.

(iii) Any drug or biologic used to treat opportunistic infections associated with acquired immune deficiency syndrome, that have been found to be medically accepted indications and that has either been approved by the federal Food and Drug Administration or recognized for that use in one of the following:

(I) The American Medical Association Drug Evaluations.

(II) The ~~United States Pharmacopoeia Dispensing Information~~ *DrugPoints*.

(III) Two articles from peer reviewed medical journals that present data supporting the proposed use or uses as generally safe and effective.

(iv) Any drug or biologic used to treat the chemotherapy-induced suppression of the human immune system resulting from the treatment of acquired immune deficiency syndrome.

(3) The department shall add any drug deemed to be approved pursuant to paragraph (1) to the Medi-Cal list of contract drugs or allow the provision of the drug as a Medi-Cal benefit, subject to utilization controls, pursuant to paragraph (2), only if the manufacturer of the drug has executed a contract with the Centers for Medicare and Medicaid Services which provides for rebates in accordance with Section 1396r-8 of Title 42 of the United States Code.

(b) Any drug deemed to be approved pursuant to paragraph (1) of subdivision (a) shall be immediately added to the Medi-Cal list

of contract drugs, and shall be exempt from the contract requirements of Section 14105.33.

(c) If it is determined pursuant to subdivision (c) of Section 14105.39 that a drug to which subdivision (a) applies should not be placed on the Medi-Cal list of contract drugs, that drug shall no longer be deemed to be approved for addition to the list of contract drugs pursuant to subdivision (a).

SEC. 19. Section 14133.2 of the Welfare and Institutions Code is amended to read:

14133.2. (a) The director shall include in the Medi-Cal list of contract drugs any drug approved for the treatment of cancer by the federal Food and Drug Administration, so long as the manufacturer has executed a contract with the Health Care Financing Administration which provides for rebates in accordance with Section 1396r-8 of Title 42 of the United States Code. These drugs shall be exempt from the contract requirements of Section 14105.33.

(b) In addition to any drug added to the list of contract drugs pursuant to subdivision (a), any drug that meets either of the following criteria and for which the manufacturer has executed a contract with the Health Care Financing Administration that provides for rebates in accordance with Section 1396r-8 of Title 42 of the United States Code, shall be a Medi-Cal benefit, subject to utilization controls, unless the contract requirements of Section 14105.33 have been complied with:

(1) Any drug approved by the federal Food and Drug Administration for treatment of opportunistic infections associated with cancer.

(2) Any drug or biologic used in an anticancer chemotherapeutic regimen for a medically accepted indication, which has either been approved by the federal Food and Drug Administration, or recognized for that use in one of the following:

(A) The American Medical Association Drug Evaluations.

(B) The ~~United States Pharmacopoeia Dispensing Information~~ *DrugPoints*.

(C) Two articles from peer reviewed medical journals that present data supporting the proposed use or uses as generally safe and effective.

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